(12) **EUROPEAN PATENT SPECIFICATION**

(54) **ARTIFICIAL HEART VALVE**

KÜNSTLICHE HERZKLAPPE

VALVULE CARDIAQUE ARTIFICIELLE

(73) Proprietor:
INNOVATIVE TECHNOLOGIES GROUP PLC
Winsford, Cheshire CW7 3PD (GB)

(72) Inventor: FISHER, John
West Park Drive, Leeds LS16 5LY (GB)

(74) Representative:
Rackham, Stephen Neil et al
GILL JENNINGS & EVERY,
Broadgate House,
7 Eldon Street
London EC2M 7LH (GB)

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- MEDICAL AND BIOLOGICAL ENGINEERING vol. 14, no. 2, March 1976, LONDON U.K. pages 122 - 129 D. N. GHISTA 'TOWARD AN OPTIMUM PROSTHETIC TRILEAFLET AORTIC-VALVE DESIGN'

EP 0 632 711 B1

Description

BACKGROUND OF THE INVENTION

The present invention relates to artificial heart valves, and more particularly to flexible leaflet heart valves as specified in the preamble of Claim 1 which are used to replace the natural aortic or pulmonary valves of the heart.

Such valves are in general known from e.g. Medical And Biological Engineering, vol. 14, no. 2, p. 122-129, March 1976 or GB-A-1 443 221 or CA-A-1 232 407.

Conventionally, ball or disk valves are used to replace natural mitral or tricuspid aortic or pulmonary valves of the heart. These artificial valves comprise a rigid frame defining an aperture and a cage enclosing a ball or a disk. When blood flows in the desired direction, the ball or disk lifts away from the frame allowing the blood to flow through the aperture. The ball or disk is restrained by the cage by struts or by a pivot. When blood tries to flow in the reverse direction, the ball or disk becomes seated over the aperture and prevents the flow of blood through the valve. The disadvantage of these valves is that the ball or disk remains in the blood stream when the blood flows in the desired direction, and this causes a disturbance to blood flow.

More recently, flexible leaflet valves have been proposed which mirror natural heart valves more closely. These valves have a generally rigid frame and flexible leaflets attached to this frame. The leaflets are arranged so that, in the closed position, each leaflet contacts its neighbour thereby closing the valve and preventing the flow of blood. In the open position, the leaflets separate from each other, and radially open out towards the inner walls of an artery in which the valve is located. The leaflets are either made from chemically treated animal tissue or polyurethane material. The leaflets must be capable of withstanding a high back pressure across the valve when they are in the closed position, yet must be capable of opening with the minimum pressure across the valve in the forward direction. This is necessary to ensure that the valve continues to correctly operate even when the blood flow is low, and to ensure that the valve opens quickly when blood flows in the desired direction.

A wide range of geometries are used to describe natural aortic valve leaflets during diastole, but these geometries cannot be used for valves made from pericardial or synthetic materials due to the approximately isotropic properties of such materials compared to the highly anistropic material of the natural valve. Consequently, different geometries have to be used to form flexible leaflet heart valves made from pericardial or synthetic materials with isotropic mechanical properties.

Conventional flexible leaflet heart valves have three substantially identical leaflets mounted onto the frame. The leaflets have a range of designs, both in the geometry of the leaflet and the variations in thickness of the leaflets. Original flexible leaflet heart valves incorporate leaflets which are spherical or conical when in the relaxed stat , that is when no pressur is acting on the leaflet. More recently, cylindrical and ellipsoidal leaflets have been proposed. These leaflet geometries are formed with an axis of revolution in a plane generally parallel to the blood flow through the valve.

DISCLOSURE OF THE INVENTION

According to the present invention, a flexible leaflet heart valve for controlling the flow of blood comprises a substantially rigid frame and a plurality of substantially identical flexible leaflets mounted on the frame, each flexible leaflet forming part of a surface of revolution having its axis of revolution lying in a plane substantially orthogonal to the direction of blood flow through the valve, characterised in that each leaflet has a shape defined by the equation:

$$z^2 + y^2 = 2R_L(x-g) - \alpha(x-g)^2$$

where:

g is the offset of the leaflet from the axis of the frame;

R_L is the radius of curvature of the leaflet at $(g,0,0)$; and

α is the shape parameter and is greater than 0 and less than 1.

A flexible leaflet valve according to the present invention has improved opening characteristics under low flow conditions. The shape of the leaflets is such that the radius of curvature of the leaflet continuously increases in two directions away from the centre point of the free edge. By varying the radius of curvature, the leaflet shape may be varied and still fit within the frame.

The value of α may be in the range of 0.2 to 0.8, but is preferably in the range 0.4 to 0.6, and more preferably is about 0.5.

Preferably, x is in the range of 0 to R_L. y is in the range between $-R_L$ and $+R_L$, and z lies in the range -1.8 R_L to +0.2 R_L.

The valve preferably includes three leaflets, and in this case the valve closure is preferably effected by the surface adjacent the free edge of each leaflet making sealing contact with the two neighbouring leaflets. The frame on which the leaflets are mounted is preferably circular in cross-section, and has a size dependent upon the size of the aorta or pulmonary artery in which the valve is to be used.

Preferably, each leaflet is made from a polyurethane material, and has a variable thickness, preferably between 0.15 mm and 0.25 mm.

BRIEF DESCRIPTION OF THE DRAWINGS

An example of a flexible leaflet heart valve according to the present invention will be described with reference to the accompanying drawings, in which:-

Figure 1 shows an overall view of the valve;
Figure 2 shows a plan of the valve; and,
Figure 3 shows a cross section of one leaflet of the valve taken along the line A - A shown in Figure 2.

DESCRIPTION OF PREFERRED EMBODIMENT

As shown in Figure 1, a flexible leaflet heart valve 1 includes three flexible leaflets 2 which are substantially identical to each other. The leaflets 2 have a free edge 4. The leaflets 2 are mounted symmetrically on a frame 3. The valve 1 is positioned in an artery with the axis of the frame 3 generally coaxial to the axis of the artery, and hence in the same direction as the blood flow along the artery. The leaflets 2 form part of a paraboloid having its axis of revolution lying in a plane orthogonal to the direction of blood flow.

Using cartesian geometry with the z direction being the direction of blood flow, the y direction orthogonal to this and extending from the centre of the free edge 4 of the leaflet 2, and the x direction being orthogonal to both the y and z directions, then the shape of the leaflet is represented by the equation:

$$z^2 + y^2 = 2R_L (x - g) - \alpha (x - g)^2$$

where:

g is the offset of the leaflet from the axis of the frame as shown in Figure 3;
R_L is the radius of curvature of the leaflet at (g, 0, 0) as shown in Figure 2; and
α is the shape parameter, and is greater than 0 and less than 1.

If $\alpha = 1$ the geometry of the leaflet 2 will be spherical. When $\alpha = 0$, the surface will be parabolic. However, for $0 > \alpha > 1$, the leaflet shape has a variable radius of curvature having its axis of revolution in the x, y plane. This allows leaflets to be produced having a shape to give the required properties which also fits within any given frame.

The valve radius, R_F as shown in Figure 3, and R_L are both in the range of 5 mm to 20 mm, g is in the range of 0 to 3 mm and α is 0.5.

Leaflets of this shape open radially away from the centre of the frame out towards the wall of the artery with a very low pressure, typically below 1 mm Hg. This is important as if the valve 1 fails to open at low pressures, the blood will cease to circulate. The shape of the leaflets 2 also ensures that they rapidly close when the blood tries to flow in the reverse direction, therefore quickly preventing the blood from flowing in this direction.

Various sizes of frame 3 may be used depending upon the size of the artery. Due to the leaflets 2, a frame radius R_F of about 13.5 mm produces a valve having an effective orifice area of approximately 2.5 cm². This typically allows approximately 4.5 litres per minute of blood to flow through, at which rate, the valve 1 has a closing regurgitant volume of less than 3 ml per stroke.

Although not shown, the valve may have only two or more than three flexible leaflets 2.

The precise size and shape of the leaflets 2 depends upon the particular size of vessel in which the valve 1 is to be used. In particular, the shape parameter α of the leaflets 2, may be varied to produce a set of valves 1 of substantially the same size but different shapes to suit most applications. Alternatively, a set of heart valves 1 may be produced all of which have the same shape, but have different sizes for particular applications.

Claims

1. A flexible leaflet heart valve for controlling the flow of blood in an artery comprising a substantially rigid frame (3), and a plurality of substantially identical flexible leaflets (2) mounted on the frame (3), each flexible leaflet (2) being formed from part of a surface of revolution having its axis of revolution lying in a plane substantially orthogonal to the direction of blood flow through the valve (1), characterised in that each leaflet (2) has a shape defined by the equation:

$$z^2 + y^2 = 2R_L (x - g) - \alpha (x - g)^2$$

where:

g is the offset of the leaflet from the axis of the frame;
R_L is the radius of curvature of the leaflet (2) at (g, 0, 0); and
α is the shape parameter and is greater than 0 and less than 1.

2. A flexible leaflet heart valve according to claim 1, in which α is in the range 0.2 to 0.8.

3. A flexible leaflet heart valve according to claim 1 or 2, in which α is within the range 0.4 to 0.6.

4. A flexible leaflet heart valve according to any of the preceding claims, in which α is substantially 0.5.

5. A flexible leaflet heart valve according to any of the preceding claims, in which x is in the range 0 to R_L, y, when present, is in the range $-R_L$ to $+R_L$, and z is in the range $-1.8R_L$ to $+0.2R_L$.

6. A flexible leaflet heart valve according to any of the preceding claims, in which the valve radius R_F and R_L are both between 5 mm and 20 mm, and g is in the range 0 to 3 mm.

7. A flexible leaflet heart valve according to any of the preceding claims including three flexible leaflets (2).

8. A flexible leaflet heart valve according to any of the preceding claims, in which the rigid frame (3) has a substantially circular cross section.

9. A flexible leaflet heart valve according to any of the preceding claims, in which the leaflets are made from polyurethane and have a variable thickness in the range 0.15 mm to 0.2 mm.

Patentansprüche

1. Als flexibles Blattventil ausgebildete Herzklappe zum Steuern des Blutstromes in einer Arterie, mit einem im wesentlichen starren Rahmen (3) und mehreren im wesentlichen identischen Blättern (2), die an dem Rahmen (3) angebracht sind, wobei jedes flexible Blatt (2) die Form eines Teils einer Rotationsfläche hat, deren Rotationsachse in einer Ebene liegt, welche in wesentlichen senkrecht zur Richtung des Blutstroms durch die Herzklappe (1) verläuft, dadurch gekennzeichnet, daß jedes Blatt (2) eine Form hat, die durch die folgende Gleichung definiert ist:

$$z^2 + y^2 = 2R_L(x-g) - \alpha(x-g)^2$$

worin:

    g der Versatz des Blattes gegenüber der Achse des Rahmens ist;
    R_L der Krümmungsradius des Blattes (2) bei (g, O, O) ist; und
    α der Formparameter ist und größer als 0 und kleiner als 1 ist.

2. Als flexibles Blattventil ausgebildete Herzklappe nach Anspruch 1, bei der α im Bereich von 0,2 bis 0,8 liegt.

3. Als flexibles Blattventil ausgebildete Herzklappe nach Anspruch 1, bei der α im Bereich von 0,4 bis 0,6 liegt.

4. Als flexibles Blattventil ausgebildete Herzklappe nach einem der vorhergehenden Ansprüche, bei der α im wesentlichen 0,5 beträgt.

5. Als flexibles Blattventil ausgebildete Herzklappe nach einem der vorhergehenden Ansprüche, bei der x im Bereich von O bis R_L, y, falls vorhanden, im Bereich von $-R_L$ bis $+R_L$ und z im Bereich von $-1,8$ R_L bis $+0,2$ R_L liegt.

6. Als flexibles Blattventil ausgebildete Herzklappe nach einem der vorhergehenden Ansprüche, bei der der Ventilradius R_F und R_L beide zwischen 5 mm und 20 mm liegen und g im Bereich von 0 bis 3 mm liegt.

7. Als flexibles Blattventil ausgebildete Herzklappe nach einem der vorhergehenden Ansprüche, die drei flexible Blätter (2) aufweist.

8. Als flexibles Blattventil ausgebildete Herzklappe nach einem der vorhergehenden Ansprüche, bei der der starre Rahmen (3) einem im wesentlichen kreisförmigen Querschnitt hat.

9. Als flexibles Blattventil ausgebildete Herzklappe nach einem der vorhergehenden Ansprüche, bei dem die Blätter aus Polyurethan bestehen und eine veränderliche Dicke im Bereich von 0,15 mm bis 0,2 mm haben.

Revendications

1. Valve cardiaque à feuillets flexibles, pour commander la circulation du sang dans une artère, comportant un cadre (3) essentiellement rigide et plusieurs feuillets flexibles (2) essentiellement identiques montés sur le cadre (3), chaque feuillet flexible (2) étant formé d'une partie d'une surface de révolution dont l'axe de révolution est situé dans un plan essentiellement orthogonal à la direction de circulation du sang à travers la valve (1), caractérisée en ce que chaque feuillet (2) présente une forme définie par l'équation:

$$z^2 + y^2 = 2R_L(x-g) - \alpha(x-g)^2$$

dans laquelle:

    g représente le décalage entre le feuillet et l'axe du cadre;
    R_L représente le rayon de courbure du feuillet (2) en (g, 0, 0); et
    α représente le paramètre de forme et est supérieur à 0 et inférieur à 1.

2. Valve cardiaque à feuillets flexibles selon la revendication 1, dans laquelle α est compris dans la plage de 0,2 à 0,8.

3. Valve cardiaque à feuillets flexibles selon la revendication 1 ou 2, dans laquelle α est compris dans la plage de 0,4 à 0,6.

4. Valve cardiaque à feuillets flexibles selon l'une

quelconque des revendications précédentes, dans laquelle α vaut essentiellement 0,5.

5. Valve cardiaque à feuillets flexibles selon l'une quelconque des revendications précédentes, dans laquelle x est compris dans la plage de 0 à R_L, y, s'il existe, est compris dans la plage de -R_L à +R_L et z est compris dans la plage de -1,8 R_L à +0,2 R_L.

6. Valve cardiaque à feuillets flexibles selon l'une quelconque des revendications précédentes, dans laquelle le rayon de la valve R_F et R_L sont tous deux compris entre 5 mm et 20 mm, et g est compris dans la plage de 0 à 3 mm.

7. Valve cardiaque à feuillets flexibles selon l'une quelconque des revendications précédentes, comportant trois feuillets flexibles (2).

8. Valve cardiaque à feuillets flexibles selon l'une quelconque des revendications précédentes, dans laquelle le cadre rigide (3) présente une section transversale essentiellement circulaire.

9. Valve cardiaque à feuillets flexibles selon l'une quelconque des revendications précédentes, dans laquelle les feuillets sont réalisés en polyuréthane et présentent une épaisseur variant dans la plage de 0,15 mm à 0,2 mm.
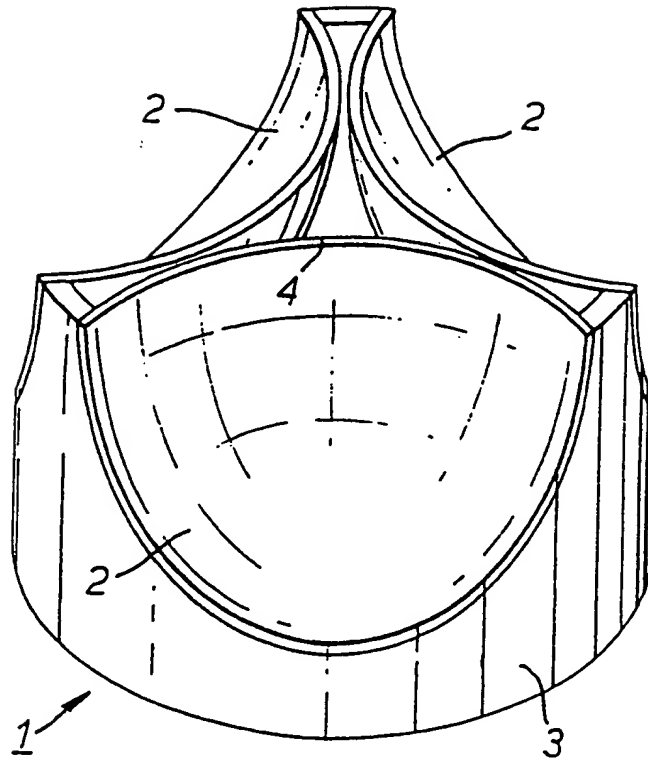
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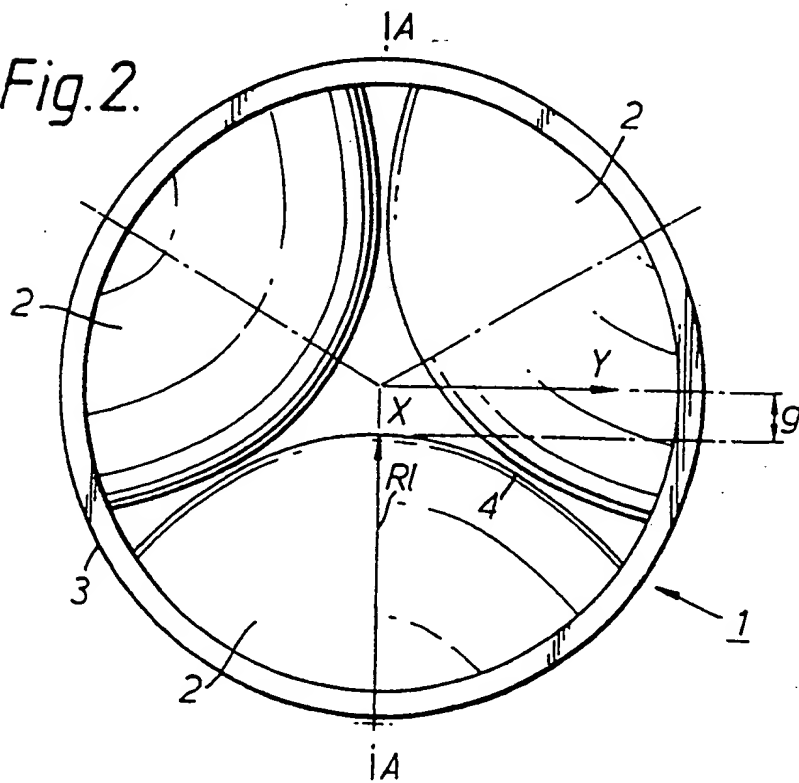
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Fig.1.

Fig.2.

Fig.3.